Atty. Dkt. No. 033948-0126



E UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GARDNER, David K. and LANE,

Michelle T.

Title:

MAMMALIAN GAMETE AND EMBRYO CULTURE MEDIA

SUPPLEMENT AND METHOD

OF USING SAME

Appl. No.:

10/764,821

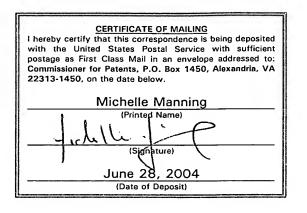
Filing Date: 01/26/2004

Examiner:

J. Eric Angell

Art Unit:

1635



## INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Mail Stop MISSING PARTS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith on Form PTO-1449 a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 C.F.R. § 1.56, including the documents cited by or submitted to the United States Patent & Trademark Office in parent application Serial No. 09/877,395. As provided in 37 C.F.R. §1.98(d), copies of the documents cited or submitted during the prosecution of application Serial No. 09/877,395, filed 06/08/2001, are not being provided since they were previously submitted to the United States Patent & Trademark Office. A copy of each remaining non-U.S. patent and non-U.S. patent application document is being submitted to comply with the provisions of 37 C.F.R. §§ 1.97 and 1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statement in a patent application filed after June 30, 2003 and in an

international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The Form PTO-1449 and accompanying documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

## RELEVANCE OF EACH DOCUMENT

An English translation of the single foreign-language document (EP 0220379) is not readily available. However, an English language abstract of the foreign language document is included with the foreign-language document.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-2350. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-2350.

Respectfully submitted,

Date June 28, 2004

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Michelle Manning

Attorney for Applicant Registration No. 50,592

Form PTO-1449		U.S. DEPARTMENT OF COMMERCE			ATTY. DOCKET NO.		SERIAL NO.		
(MODIFIED)		PATENT AND TRADEMARK OFFICE			033948-0126		10/764,821		
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EXAMINER INITIAL	REF	NUMBER	DATE	NAME CL		CLASS	SUB- CLASS	1	F PRIATE
		4,007,087	02/08/1977	Eric	sson		<u> </u>		
		4,327,177	04/27/1982	Shrimpton  Bergman et al.					
		4,804,537	02/14/1989						
		5,102,783	04/07/1992	Alke	made et al.				
5,432,160 07		07/11/1995	Hara et al.						
	5,496,720 03/05/1996 Su		Sus	ko-Parrish et al.					
		5,612,196	03/18/1997	Bec	quart et al.				
		5,096,822	03/07/1992	Ros	endrans, Jr. et al.				
		6,010,448	01/04/2000	Tho	mpson				
		6,043,092	03/28/2000	Bloc	k	:			
		6,048,728	04/11/2000	Inlov	v et al.				
		6,130,086	10/10/2000	Nak	azawa et al.				
		6,153,582	11/28/2000	Ske	nik				
		6,140,121	10/31/2000	Ellin	gton et al.	,			
			FOREIGN	PAT	ENT DOCUMENTS	_1	<u> </u>	I	
	REF	DOCUMENT	DATE		COUNTRY	CLASS	SUB-	TRANSLATION	
		NUMBER				02,00	CLASS	YES	NO
		WO 86/07377	18 Dec 1986	PCT					
		WO 99/67364	29 Dec 1999	PCT					
		WO 00/32140	8 Jun 2000	PCT	· · · · · · · · · · · · · · · · · · ·				
		WO 92/21234	10 Dec 1992	PCT					
		EP 0 220 379	3 Jul 1986	Euro	ppe				
		EP 0 248 637	2 Jun 1987	Euro	ppe				
		EP 0 521 674	29 Jun 1992	Euro	ре				
		EP 0 872 80	21 Oct 1998	Euro	ppe				
		EP 0 947 581	6 Aug 1997	Euro	ppe				
		2,199,663	11 Sep 1998	Can	ada				
		OTHER DOCU	MENTS (Includ	ing A	uthor, Title, Date, Pe	tinent Pages,	Etc.)		
		Copy of Denmark Search Report No. SE 2003 04710.							
		Kane, M. T. et al., Supports Developr Zoology, Vol. 247,	nent of Eight-Cell	Ham	fedium Containing Poly ster Embryos to Hatchi n R. Liss, Inc.	vinylalcohol, Vi ng Blastocysts,	tamins, and A	Amino Acid of Experi	ds mental

Form PTO-1449	U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO.	SERIAL NO.			
(MODIFIED)	PATENT AND TRADEMARK OFFICE	033948-0126	10/764,821			
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		FILING DATE	GROUP ART UNIT			
(Use	several sheets if necessary)	01/26/2004	1635			
	OTHER DOCUMENTS (Including A	uthor, Title, Date, Pertinent Pages,	Etc.)			
	McKiernan, S. H. et al., "Different Lots of Hamster Embryos," In Vitro Cell Dev. Bio.					
	Batt, P. A., et al., "Oxygen Concentration Embryos In Vitro," Reprod. Fertil. Dev., V		oment of Preimplanation Goat			
	Kane, M. T., "Minimal Nutrient Requirement Reproduction, Vol. 37, pp. 775-778, 1987		bryos," <i>Biology of</i>			
	Gray, C. W. et al., "Purification of an Emb Identification as Citrate," J. Reprod. Fert., Great Britain.					
	Farrar, N.C. et al., "Effects of Serum or Fa Development of Bovine Embryos In Vitro, Animal Science, September 1999.	atty Acid Supplementation of Synthetic " Abstract from a presentation at a me	Oviduct Fluid Medium on eting of the British Society of			
	Hooper, K. et al., "Toward Defined Physic Recombinant Albumin," Biology of Repro- Meeting of Society for the Study of Repro-	duction, Vol. 62, (Suppl. 1), p. 249 (Ab	stract), from 33 <sup>rd</sup> Annual			
	Gardner, D. et al., "Recombinant Human in Embryo Culture Media," <i>American Soci</i> from 56 <sup>th</sup> Annual Meeting of the American California.	ety for Reproductive Medicine, Vol. 74	. No. 3S, p. S31 (Abstract).			
	Gardner, D. et al., "Bovine Oocyte Matura Recombinant Albumin and Hyaluronan," 7 55, No. 1, p. 471 (Abstract), from Proceed Society, January 13-16, 2001, Omaha, No.	Theriogenology, An international Journ lings of the Annual Conference of the	al of Animal Reproduction, Vol.			
	Gardner, D. K. et al., "Culture of viable hu Repro., Vol. 13, Suppl. 3, June 1998, pp. Embryology.					
	Keenan, J. et al., "Recombinant human al NRK and SCC-9 cells in vitro," Cytotechno Academic Publishers.	bumin in cell culture: Evaluation of groology, Vol. 24, No. 3, 1997, pp. 243-25	owth-promoting potential for 62; published by Kluwer			
	Kjems, E. et al., "Isolation of hyaluronic ac Acta Pat. Microbiol. Scand., Sect. B, Vol.		nemically defined medium,"			
	Gene Characterization Kits, Stratagene C	atalog, 1988, p. 39.				
	Miyano, T. et al., "Effects of Hyaluronic Ac Blastocyst Stage in Vitro," Theriogenology					
	Quinn, P. et al., "Improved Pregnancy Rathe Composition of Human Tubal Fluid," Fertility Society	te in Human In Vitro Fertilization with t Fertility and Sterility, Vol. 44, No. 4, pp.	he Use of a Medium Based on 493-498, 1985; The American			
	Roth, E. et al., "Influence of Two Glutamin Cellular & Devel. Biol., Vol. 24, No. 7, pp.					
	Jones, G. M. et al., "Evolution of a Culture Human Repro., Vol. 13, No. 1, pp. 169-17 Embryology.	Protocol for Successful Blastocyst De 7, 1998; European Society for Human	evelopment and Pregnancy," Reproduction and			
	Gardner, D. K. et al., "Concentrations of Nutrients in Mouse Oviduct Fluid and Their Effects on Embryo Development and Metabolism In Vitro," <i>J Repro &amp; Fert.</i> , Vol. 88, pp. 361-368, 1990; Journals of Reproduction & Fertility Ltd., printed in Great Britain.					

Hammitt, D. G. et al., "Improved Methods for Preparation of Culture Media for in-vitro Fertilization and Gamete Intra-Fallopian Transfer," Human Repro., Vol. 5, No. 4, pp. 457-463, 1990; Oxford University Press.
Leese, H. J., "The Environment of the Preimplantation Embryo," from <i>Establishing a Successful Human Pregnancy</i> , Serono Symposia Publications from Raven Press, Vol. 66, pp. 143-154, 1990; R. G. Edwards (ed.), Raven Press, New York.
Yovich, J. et al., <i>The Management of Infertility: A Manual of Gamete Handling Procedures</i> , pp. 106-195, 1990; John Yovich and Gedis Grudzinskas, Oxford.
Lane, M. et al., "Effect of Incubation Volume and Embryo Density on the Development and Viability of Mouse Embryos In Vitro," Human Repro., Vol. 7, No. 4, pp. 558-562, 1992; Oxford University Press.
Gardner, D. K. et al., "Mouse Embryo Cleavage, Metabolism and Viability: Role of Medium Composition," Human Repro., Vol. 8, No. 2, pp. 288-295, 1993; Oxford University Press.
Gardner, D. K. et al., "Embryo Culture Systems," Handbook of In Vitro Fertilization, Trounson & Gardner (eds.), pp. 85-114, 1993; CRC Press.
Gardner, D. K. et al., "Amino Acids and Ammonium Regulate Mouse Embryo Development in Culture," Biol. Repro., Vol. 48, pp. 377-385, 1993.
Lane, M. et al., "Increase in Postimplantation Development of Cultured Mouse Embryos by Amino Acids and Induction of Fetal Retardation and Exencephaly by Ammonium Ions," J. Repro. & Fertility, Vol. 102, pp. 305-312, 1994; Journals of Reproduction & Fertility Ltd.
Gardner, D. K. et al., "Enhanced Rates of Cleavage and Development for Sheep Zygotes Cultured to the Blastocyst Stage In Vitro in the Absence of Serum and Somatic Cells: Amino Acids, Vitamins, and Culturing Embryos in Groups Stimulate Development," <i>Biol Repro.</i> , Vol. 50, pp. 390-400, 1994.
Gardner, D. K., "Mammalian Embryo Culture in the Absence of Serum or Somatic Cell Support," <i>Cell Biol.Int'I</i> , Vol. 18, No. 12, pp. 1163-1179, 1994; Academic Press Ltd.
Barnes et al., "Blastocyst Development and Birth After In-Vitro Maturation of Human Primary Oocytes, Intracytoplasmic Sperm Injection and Assisted Hatching," <i>Human Repro.</i> , pp. 3243-3247, 1995; published by Oxford Univ. Press, Oxford.
Gardner, D. K. et al., "Alleviation of the '2-Cell Block' and Development to the Blastocyst of CF1 Mouse Embryos: Role of Amino Acids, EDTA and Physical Parameters," <i>Human Repro.</i> , Vol. 11, No. 12, pp. 2703-2712, 1996; European Society for Human Reproduction and Embryology.
O'Brien, J. K. et al., "Developmental Capacity, Energy Metabolism and Ultrastructure of Mature Oocytes from Prepubertal and Adult Sheep," Repro. Fertil. Dev., Vol. 8, pp. 1029-1037, 1996.
Schramm, R. D. et al., "Development of in-vitro-fertilized Primate Embryos into Blastocysts in a Chemically Defined, Protein-Free Culture Medium," <i>Human Repro.</i> , Vol. 11, No. 8, pp. 1690-1697, 1996; published by European Society for Human Reproduction and Embryology.
Gardner, D. et al., "Complex Physiologically Based Serum-Free Culture Media Increase Mammalian Embryo Development", from 10 <sup>th</sup> World Congress on In Vitro Fertilization and Assisted Reproduction, Vancouver, Cana, May 24-28, 1997, pp. 187-191; Monduzzi Editore S.p.A Bologna (Italy).
Gardner, D. K. et al., "Culture and Selection of Viable Blastocysts: A Feasible Proposition for Human IVF?," Human Repro Update, Vol. 3, No. 4, pp. 367-382, 1997; European Society for Human Reproduction and Embryology.
Lane, M. et al., "Differential Regulation of Mouse Embryo Development and Viability by Amino Acids," J. Repro. & Fertility, Vol. 109, pp. 153-164, 1997; Journals of Reproduction & Fertility Ltd.
Lane, M. et al., "Animal Experimentation: Nonessential Amino Acids and Glutamine Decrease the Time of the First Three Cleavage Divisions and Increase Compaction of Mouse Zygotes In Vitro," .J. Assisted Repro. and Genetics, Vol. 14, No. 7, pp. 398-403, 1997; Plenum Publishing Corporation.
Abeyderra, L. R. et al., "Fertilization and Subsequent Development In Vitro of Pig Oocytes Inseminated in a Modified Tris-Buffered Medium with Frozen-Thawed Ejaculated Spermatozoa," Biol. Repro., Vol. 57, pp. 729-734, 1997.
Keskintepe, L. et al., "Caprine Blastocyst Formation Following Intracytoplasmic Sperm Injection and Defined Culture," Zygote, Vol. 5 (August), pp. 261-265, 1997; Cambridge University Press.

Gardner, D. K. et al., "Culture and Transfer of Human Blastocysts Increases Implantation Rates and Reduces the Need for Multiple Embryo Transfers," Fertility and Sterility, Vol. 69, pp. 84-88, 1998; Elsevier Science, New York.
Gardner, D. K., "Development of Serum-Free Media for the Culture and Transfer of Human Blastocysts," Human Repro. Vol. 13, Suppl. 4, pp. 218-225, 1998; European Society for Human Reproduction and Embryology.
Gardner, D. K. et al., "Elimination of High-Order Multiple Gestations by Blastocyst Culture and Transfer," Female Infertility Therapy: Current Practice, Z. Shoham et al., eds., pp. 267-274, 1998; Martin Dunnitz, London.
Gardner, D. K., "Improving Embryo Culture and Enhancing Pregnancy Rate," Female Infertility Therapy: Current Practice, Z. Shoham et al., eds., pp. 283-299, 1998; Martin Dunnitz, London.
Gardner D. et al., "Controversies in Assisted Reproduction and Genetics: Human Embryo Viability: What Determines Developmental Potential, and Can It Be Assessed?," J. Assisted Repro. & Genetics, Vol. 15, No. 8, pp. 455-458, 1998; Plenum Publishing Corporation.
Gardner, D. K., "Changes in Requirements and Utilization of Nutrients During Mammalian Preimplantation Embryo Development and Their Significance in Embryo Culture," <i>Theriogenology</i> , Vol. 49, pp. 83-102, 1998; Elsevier Science, Inc.
Lane, M. et al., "Amino Acids and Vitamins Prevent Culture-Induced Metabolic Perturbations and Associated Loss of Viability of Mouse Blastocysts," <i>Human Repro.</i> , Vol. 13, No. 4, pp. 991-997, 1998; European Society for Human Reproduction and Embryology.
Gardner, D. K., "Embryo Development and Culture Techniques," <i>Animal Breeding</i> . <i>Technology for the 21<sup>st</sup> Century</i> , A. J. Clark, ed., pp. 13-46, 1998; Harwood Academic Publishers.
Staessen, C. et al., "Controlled comparison of commercial media for human in-vitro fertilization: Ménézo B2 medium versus Medi-Cult universal and BM1 medium," <i>Human Repro.</i> , Vol. 13, No. 9, pp. 2548-2554, 1998; European Society for Human Reproduction and Embryology.
Cited pages from the Gibco catalogue. No other information avaliable.